



# Health Care in Russia

Making Inroads into the Pharmaceutical and Medical Device Markets

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The United States and Russia have an enduring relationship that has traversed the distance from adversarial to collaborative. The current relationship between Russia and the United States is one of close alliance and partnership. This partnership extends to business and government alike, and several industry dialogues are emerging to encourage Russia's economic development and help U.S. firms gain access to new markets. One of those areas is health care and specifically the pharmaceutical and medical device sectors. In an effort to liberalize the health care market in Russia, the United States government has established a government working group, which includes training programs designed to assist Russia in developing standards, regulations, and a legal framework to help the industry flourish as well as open the market to U.S. manufacturers. Despite the problems and barriers facing the health care industry in Russia, there are still many opportunities for U.S. firms.

Russia's health care sector is experiencing sustained growth and is on target to

be a promising export market for U.S. manufacturers of medical devices and pharmaceutical products. However, due to redundancy in testing, a lack of a transparent regulatory system, inconsistent standards, and instances of preferential treatment and corruption, manufacturers within and outside of Russia often find it difficult to meet the demands of the market.

## MEDICAL DEVICES

The 1998 economic crisis served as a spur for a number of Russian medical equipment and device manufacturers, which, having taken advantage of the sharp rise in prices of imported medical equipment, managed to increase their share of the total market. In general, however, imported medical equipment and supplies still play a predominant role and currently supply 71 percent of the total market. Despite the fact that the quality of some of the medical devices and supplies produced in Russia has improved, it is in many cases not up to comparable foreign products. Foreign-made, high-end medical equipment, sophisticated medical devices, and many medical products

and supplies in the majority of cases do not have Russian analogues.

Russia's existing customs classification of medical equipment in two groups (medical equipment itself and medical items, or supplies) sometimes causes confusion at ports of entry. The customs authorities refer to the duration of the registration certificate issued by the Ministry of Health as a basis for determining the VAT rate. Classification systems used in Russia contribute to the fact that the whole regulatory system is less adapted to the general trend of harmonization of global approaches to regulating the medical device industry, and make it more difficult for the Russian medical equipment industry to be more involved in international trade.

## PHARMACEUTICALS

Prior to Russia's economic crisis, pharmaceuticals was one of the fastest-growing and most lucrative markets in Russia. The pharmaceutical market in Russia today continues to present great potential, but the obstacles to foreign investment cannot be underestimated. The major obstacles in developing the pharmaceutical market in Russia are

lack of transparency in the registration and certification systems, as well as inadequate IPR protection and a large percentage of counterfeit medicines. According to various analysts, counterfeit drugs currently represent up to 12 percent of the pharmaceutical market.

Russia has a developed pharmaceutical market with major Western drug manufacturers represented in the country. Despite the fact that total value is still lower than in 1997, the pharmaceutical market has been growing rapidly over the past three years. By 2004–2005, the market is expected to fully recover. In 1997 the Russian pharmaceutical market reached its highest pre-crisis level of \$3.1 billion. The market was reduced by the economic crisis to \$1.7 billion in 1999. The total value of the pharmaceutical market in 2002 was estimated at \$2.9 billion. It is forecast that in 2003 the market will reach the pre-crisis level. The Russian pharmaceutical market appears to present good opportunities to Western drug manufacturers, especially in the high-end quality product segment. Best prospects for U.S. pharmaceutical exports to Russia include cardiovascular, cancer, asthma, neurological and hormonal drugs, as well as insulin, antibiotics, analgesics, vitamins, vaccines, and psychotropic drugs. According to the State Customs Committee, Russia's pharmaceutical imports totaled \$2.24 billion in 2003. Total imports from the United States in 2003 totaled \$156 million.

#### COLLABORATION AND TRAINING

Working hand in hand, the pharmaceuticals and medical device industries are providing training for Russian officials on topics that affect the Russian health care industry, including global harmonization, the role of standards in regulation,

risk management for medical devices, and incorporation of U.S. and EU medical device regulatory systems. A formal framework for training culminated in June 2003 in Russia, where a host of U.S. officials and industry professionals



guided approximately 200 participants through sessions that touched on key issues for the industry. The training sessions were divided between pharmaceuticals and medical devices.

The goals of the training program were to:

- Reduce review times for regulatory approvals in Russia for medical devices and pharmaceutical products;
- Ensure better enforcement in limiting the use of counterfeit drugs on the Russian market;
- Encourage participation of Russian medical device regulators in international fora, in particular, the Global Harmonization Task Force; and
- Reduce costs for U.S. medical product manufacturers for regulatory

compliance in exporting their products to Russia.

#### Medical Devices

Personnel conducting the training sessions not only provided information relevant to the topics but also responded to numerous questions from the participants. Some of the topics covered during the training session included the Global Harmonization Task Force (GHTF), quality systems for medical devices, the role of standards for regulations, risk management, incorporation of standards into U.S. and EU medical-device regulatory systems, global activities toward regulatory harmonization, and the U.S.-EU medical devices mutual recognition agreement.

Topics that were discussed during the training touched on key areas that will help define the medical device market in Russia:

**Definition of a medical product:** Russia uses a unique process for defining “medical devices” and “medical equipment,” both of which are open to interpretation. Essentially medical devices are classified as products that have relatively short life spans under five years, and medical equipment has life spans greater than five years. In practice, there are no clear criteria to determine whether a medical product is in the medical equipment or the medical device category.

**Testing:** Russia tests most medical devices at Ministry of Health laboratories. The trainers for the June 2003 Russia regulatory seminar noted that the EU and U.S. no longer perform product testing as part of the medical device approval process. It is far more effective to ensure product safety through plant auditing, quality systems, and post market vigilance.

**Regulatory system based on existing model:** It was recommended that Russia should eventually abandon its own unique regulatory system, in favor of a new system based upon certain U.S. or EU practices, or, preferably, based upon GHTF guidance documents. It is redundant for Russia to subject FDA-approved or CE-marked medical devices to further testing or reviews, since this does not enhance public safety and only makes the process of getting advanced medical technologies to Russian citizens a more lengthy and costly process.

### Pharmaceuticals

Topics covered in the training on pharmaceuticals included an overview of the FDA, quality, safety and efficacy general approaches, FDA registration (new drugs/generic drugs), certification programs, and the role of product testing.

**Definition of registration and certification:** Several attempts were made to explain that the FDA does not “certify” pharmaceutical products, as this is the responsibility of the manufacturer. The FDA registers a product and expects that the product be produced according to specifications mutually agreed to by the applicant and the FDA.

**Standards:** The instructors pointed out that it is far more effective to ensure product safety through plant auditing, quality systems, and post market vigilance.

There was also a session on ways to combat counterfeit products. Other issues covered included government measures to combat counterfeit pharmaceuticals. Both these presentation elicited many questions, which emphasized the importance of allowing the Russian Ministry of Health, and specifically the Pharmaceutical Inspection Department, necessary powers to properly act against counterfeiters.

Finally, a presentation was given entitled the role of patents, intellectual property

rights, and data exclusivity. Specifically highlighted was the important role the Ministry of Health plays in protecting data and the need to exercise controls over all documents provided by the pharmaceutical applicants.

Building on the initial success of the training held in Moscow, a delegation of Russian health care officials visited Washington, D.C., in October 2003. The focus of their visit was to meet with several U.S. bodies that play an integral role in the health care industry. The delegation had appointments with the National Institute of Standards and Technology, National Institutes of Health, U.S. Pharmacopoeia, and the Food and Drug Administration. The delegation was in Washington primarily for the second meeting of the Russian-American Interagency Coordination Council on Harmonization in the Health Care Sector.

As a result of the meeting in October, the council formalized a plan that puts forth a future commitment to continue work on the exchange of regulatory information and experience to help Russia develop a sound health care strategy. ■

